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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,637	08/07/2001	Lawrence J. Marnett	N-6138 RSM	2070

7590 02/28/2002

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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/28/2002

J

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,637

Applicant(s)

MARNETT ET AL.

Examiner

Misook Yu

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-39, drawn to Cox-2 specific assay, classified in class 435, subclass 25.
- II. Claims 40-49, drawn to in vivo assay, classified in class 424, subclass 9.1.
- III. Claims 50-60, drawn to testing treatment effectiveness, classified in class 424, subclass 9.2.
- IV. Claims 61-66, and 79 drawn to metabolite compounds, classified in class 554, subclass 117.
- V. Claims 67-71, drawn to a process of making labeled metabolites, classified in class 435, subclass 63.
- VI. Claims 72-73, drawn to an alternate process of making labeled metabolites, classified in class 435, subclass 63.
- VII. Claims 74-77, drawn to an alternate process of making labeled metabolites, classified in class 435, subclass 63.
- VIII. Claim 78, 80, and 81, drawn to article of manufacture containing antibody and instructions, and antibody classified in class 424, subclass 130.1.
- IX. Claim 82 and 84, drawn to a process preparing antigen, classified in class 435, subclass 41.
- X. Claim 83, drawn to process for preparing for antibody, classified in class 435, subclass 325.
- XI. Claim 85, drawn to a composition comprising a prostaglandin D₂-glycerol ester, classified in class 525, subclass 10.
- XII. Claim 86, drawn to a composition comprising 6-keto-prostaglandin, classified in class 522, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV, VIII, XI, XII (products) and I, II, III (processes) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product groups IV, VIII, XI, XII are materially different alternative uses of process groups I, II, III.

Inventions IV (product) and V, VI, VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process groups V, VI, VII are materially different alternate methods of making product group IV.

Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, group IX requires chemical synthesis and group X requires biological processes.

Group 1 contains claims generic to a plurality of disclosed patentably distinct species (listed in claims 3 and 38) comprising prostaglandin H₂-glycerol ester, prostaglandin E₂-glycerol ester, 15-keto-prostaglandin E₂-glycerol ester, 13,14-dihydro-15-keto-prostaglandin E₂-glycerol ester, prostaglandin D₂-glycerol ester, prostaglandin F_{2α}-glycerol ester, thromboxane A₂-glycerol ester, prostacyclin-glycerol ester, 6-keto-prostaglandin F_{1α}-glycerol ester, prostaglandin A₂-glycerol ester, and prostaglandin B₂-glycerol ester. The metabolites are patentably distinct because they are different in chemical structure. If group 1 is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species (listed in claims 3 and 38), even though this requirement is traversed.

Group IV contains claims generic to a plurality of disclosed patentably distinct species (listed in claim 63). The metabolites are patentably distinct because they are

Art Unit: 1642

different in chemical structure. If group 1V is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species (listed in claim 63), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Several inventions are independent and distinct for the reasons given above. They have acquired a separate status in the art as shown by their different classification and require independent searches. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/923,637
Art Unit: 1642

Page 5

Misook Yu
February 21, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600